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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,798	08/24/2001	Nathan Karin	01/22078	3702

7590

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/856,798**

Applicant(s)  
**Karin**

Examiner  
**Anne Marie Wehbé**

Art Unit  
**1632**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-34 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **Election/Restriction**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 8-11, 34, drawn to antibodies capable of binding to an interferon gamma inducing factor and the therapeutic use of said antibodies in vivo, classified in classes 530 and 424, subclasses 187.1 and 130.1 respectively.
- II. Claims 14-20, 28-33, drawn to pharmaceutical compositions comprising vectors encoding a polypeptide capable of inducing antibodies to an interferon gamma inducing factor, and the therapeutic use of said vectors in vivo, classified in classes 536, 435, and 514, subclasses 23.1, 320.1, and 44 respectively.
- III. Claims 6-7, drawn to methods of treating an animal comprising the administration of cells which produce an antibody, classified in classes 435 and 424, subclasses, 326 and 93.21 respectively.
- IV. Claims 12-13, drawn to a pharmaceutical composition comprising interferon gamma inducing factor and the therapeutic use of said polypeptide in vivo, 530 and 514, subclasses 300 or 350, and 2 respectively
- V. Claims 21-27, drawn to a pharmaceutical composition comprising cells genetically modified to encode interferon gamma inducing factor and the therapeutic use of said cells in vivo, classified in classes 435 and 424, subclasses, 325 and 93.2 respectively.

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The inventions are distinct, each from the other because of the following reasons.

Inventions I-V are patentably distinct in that polypeptides, nucleic acids, antibodies, and cells expressing a protein or antibody are substantially different in structural, physical, and biological properties, are made using different reagents and methods, and can be used for substantially different purposes. In particular, note that the polypeptide can be made synthetically and does not require the nucleic acid, and that the antibody can be naturally occurring and does not require the polypeptide for its manufacture. Further, while cells transfected with a vector do utilize the nucleic acid, the transfected cells are structurally and functionally different from isolated nucleic acids and vectors. Further, the vectors can be used for purposes other than making transfected cells, such as their use in in vitro hybridization assays. In regards to in vivo administration, it is further noted that nucleic acids, polypeptides, and antibodies have completely different modes of operation in vivo based on the different biological properties of the compounds. Inventions II and V are further patentably distinct in that the cells of invention II encode an antibody, whereas the cells of invention V encode an interferon gamma inducing factor. As such, the transfected cells of invention II are structurally and functionally different from the transfected cells of invention V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

**ANNE M. WEHBE' PH.D**  
**PRIMARY EXAMINER**

